Ciba Specialty Chemicals
North America

8EHQ-0601-14949

Ciba

June 6, 2001

Via Federal Express
Confidential

US Environmental Protection Agency
OPPT Document Control Office TS 7407
Attention: Section 8(e)
Ariel-Rios Building
1200 Pennsylvania Avenue NW
Washington, DC 20460

SANITIZED COPY

Subject: TSCA 8(e) Notice - CG40-0980 (TKA 40234)

Dear Section 8(e) Coordinator:

This letter contains Confidential Business Information. Confidential Information bracketed {}.

In accordance with EPA's March 16, 1978 Policy Statement on Section 8(e) reporting under the Toxic Substances Control Act (TSCA), the EPA's June, 1991 TSCA Section 8(e) Reporting Guide, Ciba Specialty Chemicals Corporation wishes to bring to the attention of the Environmental Protection Agency the results observed in a 72-hour algal growth study with an experimental additive, CG40-0980. CG40-0980 chemically is { }. A CASRN has not been assigned to this material.

We are enclosing a copy of the study ***"Toxicity of CG40-0980 (TKA 40234) To Scenedesmus Subspicatus in a 72-Hour Algal Growth Screening Test"*** RCC,Ltd, CH-4452, Itingen, Switzerland; RCC Study Number 808705.

A 72-hour algal growth test was conducted for CG40-0980 with Scenedesmus subspicatus. The test material was not soluble at 100 mg/L, and water accomodated fractions (WAF) were prepared with loading rates of 1, 10, and 100 mg/L. Inhibition of algal growth was determined from the area under the growth curves and the specific growth rates for exponentially growing cultures. The EC50 for growth inhibition was found to be < 1 mg/L (WAF).

Based upon current EPA guidelines, it is felt these results warrant reporting under TSCA 8(e). A sanitized copy of this letter is also enclosed; the report does not contain Confidential Business Information (CBI). A CBI Substantiation for this product is also submitted pursuant to TSCA 8(e) requirements. Please call the undersigned if you have any questions concerning this submittal.

Respectfully,

Ciba Specialty Chemicals Corporation

COMPANY SANITIZED

TLM

Thomas Barber
Manager, Regulatory Compliance

SANITIZED COPY

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REPORT

Study Title:

TOXICITY OF
CG 40-0980 (TKA 40234)
TO *SCENEDESMUS SUBSPICATUS*
IN A 72-HOUR ALGAL GROWTH SCREENING TEST

Study Director:

Dr. Armin Peither

Study Completion Date:

April 26, 2001

Test Facility:

RCC Ltd
Environmental Chemistry &
Pharmanalytics Division
CH-4452 Itingen / Switzerland

Sponsor:

Ciba Specialty Chemicals Inc.
Additives Division
CH-4002 Basel / Switzerland

RCC Study Number:

808705

RCC

SIGNATURES

Study Director: Dr. Armin Peither

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Date: April 26, 2001

Management: Mr. Markus Arenz

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Date: April 26, 2001

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PREFACE

GENERAL

Study Title:	Toxicity of CG 40-0980 (TKA 40234) to *Scenedesmus subspicatus* in a 72-hour algal growth screening test
Sponsor:	CIBA Specialty Chemicals Inc. Additives Division, P.O. Box, WRO-1045.1.35 CH-4002 Basel / Switzerland
Monitoring Scientist:	Dr. Peter Dollenmeier
Testing Facility:	RCC Ltd Environmental Chemistry & Pharmanalytics Division Zelgliweg 1 CH-4452 Itingen / Switzerland

RESPONSIBILITIES

Study Director:	Dr. Armin Peither
Technical Coordinator:	Mr. Roger Thommen

SCHEDULE

Experimental Starting Date:	March 19, 2001
Experimental Completion Date:	March 26, 2001
Study Completion Date:	April 26, 2001

1 MATERIALS AND METHODS

1.1 TEST ITEM

Test Item:	CG 40-0980 (TKA 40234)
Batch No.:	SE 6521-004
Purity:	Research sample (not analyzed)
Expiry Date:	February 26, 2002
Storage conditions:	At room temperature at about 20 °C, in the dark

1.2 EXPERIMENTAL CONDITIONS

The toxicity of the test item CG 40-0980 (TKA 40234) to *Scenedesmus subspicatus* was determined in a 72-hour static test based on the EU Commission Directive 92/69/EEC, C.3 (1992), and the OECD Guideline for Testing of Chemicals, No. 201, (1984).

The test was started (0 hours) by inoculation of a biomass of 10.000 algal cells per ml test medium. These cells were taken from an exponentially growing pre-culture, which was set up about 3 days prior to the test at the same conditions as in the test.

The test design included two replicates for each test concentration and the control. Volumes of 15 ml algal suspension per replicate were continuously stirred by magnetic stirrers in 50 ml Erlenmeyer flasks.

Inhibition of algae growth was determined from the area under the growth curves (AUC) and the specific growth rates μ for exponentially growing cultures.

Water temperature:	21 °C during the test period
Light conditions:	Continuously illuminated at a light intensity between 8400 and 9200 Lux
Test duration:	72 hours
Test water:	Reconstituted nutrient solutions according to the test guidelines

1.3 DOSAGE AND CONCENTRATIONS

According to a pre-experiment, the test item is not soluble at a concentration of 100 mg/l in test water. Therefore, three WAFs (Water Accommodated Fractions) with test item loading rates of 1, 10 and 100 mg/l were prepared as follows:

Three individual mixtures were prepared by weighing adequate amounts of the test item by means of an analytical balance: 3.1, 10 and 30 mg test item were suspended in 3000, 1000 and 300 ml test water, respectively. The test item was dispersed in the test media by ultrasonic treatment for 15 minutes. Then the mixtures were stirred by a magnetic stirrer at room temperature in the dark over 96 hours to dissolve respectively disperse a maximum concentration of the test item in the test media. No auxiliary solvent or emulsifier was used.

After the stirring period just before the preparation of the test media, each mixture was filtered through a membrane filter (Schleicher & Schuell, Type NC45, pore size 0.45 µm). The three filtrates and a control (test water without test item) were tested in parallel.

2 RESULTS

The test item had a nearly complete inhibitory effect on the growth (biomass and growth rate) of *Scenedesmus subspicatus* after the exposure period of 72 hours at the loading rates of 1.0, 10 and 100 mg/l (Table 1 to 3), indicating a high toxic effect of the test item.

Table 1: Algal cell densities at the end of the test period of 72 hours

Loading rate / Treatment	Flask No.	Density of Algal Cells after 72 hours*	
Control	1	54.2	49.9
	2	54.8	54.4
	m	53.33	
	s	1.80	
1.0 mg/l	1	3.2	2.5
	2	2.8	2.0
	m	2.62	
	s	0.32	
10 mg/l	1	3.3	2.9
	2	2.5	2.0
	m	2.67	
	s	0.60	
100 mg/l	1	2.4	2.2
	2	2.2	2.0
	m	2.20	
	s	0.14	

m: mean value; s: standard deviation

*Algal counts are divided by 10'000; at the start, 10'000 algal cells/ml were incubated

Table 2: Areas under the growth curves (AUC) and percentage inhibition of AUC during the test period

Loading rate / Treatment	Areas under the growth curves (AUC) and % inhibition of AUC 0-72 h	
	AUC	I_{AUC} (%)
Control	1884	0
1.0 mg/l	59	96.9
10 mg/l	60	96.8
100 mg/l	43	97.7
E_bL50	< 1.0 mg/l	
95% C.I.	n.d.	

95% C.I: 95% confidence interval
n.d.: For the present data, this value could not be determined

Table 3: Growth rates μ and percentage inhibition of μ during the test period

Loading rate / Treatment	Growth rate μ (1/day) and % inhibition of μ 0-72 h	
	μ (1/day)	I_μ (%)
Control	1.33	0
1.0 mg/l	0.32	75.8
10 mg/l	0.32	75.6
100 mg/l	0.26	80.2
$E_\mu L50$	< 1.0 mg/l	
95% C.I.	n.d.	

95% C.I: 95% confidence interval
n.d.: For the present data, this value could not be determined

Table 4: pH-values and temperatures in the test media at the start and end of the test

Loading rate / Treatment	pH-values	
	Start	End
Control	7.9	8.2
1.0 mg/l	7.9	7.9
10 mg/l	7.9	7.9
100 mg/l	7.8	7.8

Table 5: Appearance of the test media during the test period

Loading rate / Treatment	Appearance of the test item in the test media
1.0 mg/l	no remarkable observations, clear test solution
10 mg/l	no remarkable observations, clear test solution
100 mg/l	no remarkable observations, clear test solution